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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,103	03/10/2004	Hiroshi Takiguchi	119037	2367
25944 7590 10/29/2007 OLIFF & BERRIDGE, PLC P.O. BOX 320850			EXAMINER	
			STEELE, AMBER D	
ALEXANDRIA, VA 22320-4850			ART UNIT	PAPER NUMBER
			1639	
			MAIL DATE	DELIVERY MODE
			10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/796,103	TAKIGUCHI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Amber D. Steele	1639				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tir vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 29 Au  2a) This action is <b>FINAL</b> 2b) This  3) Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final.  nce except for formal matters, pro					
Disposition of Claims						
4) ⊠ Claim(s) 1-23 is/are pending in the application.  4a) Of the above claim(s) 10 and 19-23 is/are w  5) □ Claim(s) is/are allowed.  6) ⊠ Claim(s) 1-9 and 11-18 is/are rejected.  7) □ Claim(s) is/are objected to.  8) □ Claim(s) are subject to restriction and/or	vithdrawn from consideration.					
Application Papers						
9) ☐ The specification is objected to by the Examine 10) ☑ The drawing(s) filed on 10 March 2004 is/are: a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) ☐ The oath or declaration is objected to by the Ex	a) $\boxtimes$ accepted or b) $\square$ objected t drawing(s) be held in abeyance. Se ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
<ul> <li>12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a)  All b)  Some * c) None of: <ol> <li>Certified copies of the priority documents have been received.</li> <li>Certified copies of the priority documents have been received in Application No</li> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

## **DETAILED ACTION**

# Status of the Claims

1. The preliminary amendment received on March 10, 2004 amended claim 19.

The amendment to the claims received on August 29, 2007 amended claims 1, 2, 5, 18, 20, and 21 and canceled claims 24-25.

Claims 1-23 are currently pending.

Claims 1-9 and 11-18 are currently under consideration.

2. Please note: the status identifier for present claim 10 is listed as "original". However, claim 10 is withdrawn. In order to be considered fully responsive to the present Office action, applicants must submit a new claim set with the proper status identifiers. Please refer to MPEP § 714 (section II F) and 37 CFR 1.121.

## Election/Restrictions

- 3. This application contains claims 19-23 drawn to inventions nonelected with traverse in the reply filed on August 22, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
- 4. In the replies received on November 27, 2006 and March 9, 2007, applicants elected with traverse a probe according to claim 3 wherein  $L^3$  is a  $C_6$  alkylene group and  $L^4$  is a polyethylene glycol phosphate group as the species of probe; a compound according to formula (I) wherein  $L^1$  is a  $C_6$  alkylene group,  $L^2$  is a single bond, and R is a hydroxyl group as the species of

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compound; and HS are hydrogen and sulfur, respectively. Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

# Rejoinder Request

5. Applicants request rejoinder of nonelected method claims 19, 22, and 23 and nonelected product claims 20 and 21 in view of applicants belief that the elected method claims are allowable and in view of *In re Ochiai*.

As applicants clearly stated in the response received on page 12, third paragraph in the reply received on August 29, 2007, "in the case of an <u>elected product</u> claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim (emphasis added)."

Applicants are respectfully reminded that the <u>process</u> of claims 1-18 was elected in the response received on August 22, 2006. Therefore, rejoinder based on *In re Ochiai* is not proper because applicants have elected a <u>process</u> and not a product. In addition, the process as claimed is not allowable (please refer to the rejections below).

#### Priority

- 6. The present application claims foreign priority to JP 2003-086362 filed March 26, 2003.
- 7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, a translation of JP 2003-086362 has not been provided.

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#### Invention as Claimed

8. A method for immobilizing nucleic acid on a solid phase substrate by co-adsorption comprising: (a) bringing the solid phase substrate into contact with a composition comprising a total concentration of 0.1 to 2  $\mu$ M of a nucleic acid as a probe and a compound or a salt thereof wherein the compound has a formula represented by HS-L<sup>1</sup>-L<sup>2</sup>-R wherein L<sup>1</sup> is a single bond or a C<sub>1-15</sub> alkylene group; L<sup>2</sup> is a single bond, a nucleic acid, a polyethylene glycol group, -CO-NH-, or -NH-CO-; and R is a hydroxyl group, an amino acid group, a ferrocenyl group, or a carboxyl group, and L<sup>1</sup> and L<sup>2</sup> are not both single bonds and (b) incubating the composition in contact with a surface of the solid phase substrate and variations thereof.

Please note: claims 15 and 18 recite "may" further comprise and "may" also, therefore, the limitations are considered optional.

## **Maintained Objections**

## Claim Objections

- 9. Claims 1-9 and 11-18 are objected to because of the following informalities: the claims comprise various Markush groups but are not in proper Markush format (i.e. either (a) R is selected from the group consisting of A, B, and C or (b) wherein R is A, B, or C).
- A. Claim 1 recites "L¹ is a single bond or a C<sub>1-15</sub> alkylene group" wherein the second alternative (i.e. C<sub>1-15</sub> alkylene group) comprises multiple species. Either "L¹ is a single bond or an alkylene group" or "L¹ is a single bond, a C₁ alkylene, a C₂ alkylene, C₃ alkylene, a C₄ alkylene, a C₅ alkylene, a C₆ alkylene, C₃ alkylene, a C₆ alkylene, a

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B. Claim 1 recites L2 is selected from the group consisting of a single bond, a nucleic acid, a polyethylene glycol group, -CO-NH-, or -NH-CO-. Either L2 is selected from the group consisting of a single bond, a nucleic acid, a polyethylene glycol group, -CO-NH-, <u>and</u> – NH-CO- (emphasis added) or L2 is a single bond, a nucleic acid, a polyethylene glycol group, -CO-NH-, or -NH-CO- is suggested.

- C. Claim 1 recites R is selected from the group consisting of a hydroxyl group, an amino group, a ferrocenyl group, or a carboxyl group. Either R is selected from the group consisting of a hydroxyl group, an amino group, a ferrocenyl group, and a carboxyl group (emphasis added) or R is a hydroxyl group, an amino group, a ferrocenyl group, or a carboxyl group is suggested.
  - D. Please also refer to claims 2-3 and 11.

Please refer to MPEP § 2173.05(h). Appropriate correction is required.

## Withdrawn Objection

10. The objection of claim 2 regarding the acronyms CNA and HNA is withdrawn in view of the claim amendments received on August 29, 2007.

## Withdrawn Rejections

- 11. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants persuasive arguments.
- 12. The rejection of claims 1-9 and 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention is withdrawn in view of the claim amendments received on August 29, 2007 clarifying R, L<sup>1</sup>, and L<sup>2</sup>.

13. The rejection of claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the disclosure on page 12, lines 4-11.

#### **Maintained Rejections**

14. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. In addition, the rejections may have been altered to reflect the claim amendments or to clarify issues presented in the arguments by applicants.

# Claim Rejections - 35 USC § 102

15. Claims 1-9 and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson et al. The effect of surface probe density on DNA hybridization Nucleic Acids Research 29(24): 5163-5168, 2001.

For present claims 1, 6-9, 11-12, and 18, Peterson et al. teach methods for immobilizing nucleic acids on a solid phase substrate comprising (a) contacting a nucleic acid probe and a duplex (i.e. compound) of formula HSC<sub>6</sub>-nucleic acid (e.g. HS-L<sup>1</sup>-L<sup>2</sup>-R wherein L<sup>1</sup> is C<sub>6</sub>, L<sup>2</sup> is a single bond, and R is natural hydroxyl on 3' end of nucleic acid) with a solid support and (b) incubating the probe, compound, and solid support wherein the concentration of the probe, target, and duplex solutions are 1  $\mu$ M (please refer to entire document particularly Table 1 and Materials and Methods section). In addition, Peterson et al. teach mercaptohexanol (please refer to entire document particularly Materials and Methods section). Please note: the Office does not

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have the facilities and resources to provide the factual evidence needed in order to determine the ratio of the probe and duplex provided by Peterson et al. correlate to the 60/40 or 40/60 ratio as presently claimed in claim 8. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the ration is different from the ones taught by the prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

For present claim 2, Peterson et al. teach ssDNA as the nucleic acid probe (please refer to entire document particularly Table 1).

For present claims 3-4, Peterson et al. teach 5' end of the nucleic acid probe as formula of HSC<sub>6</sub>single bond or HSC<sub>6</sub>spacer (e.g. HS-L3-L4 wherein L3 is C6 and L4 is a single bond or spacer; please refer to entire document particularly Table 1).

For present claim 5, Peterson et al. teach probe with nucleic acid (e.g. spacer; please refer to entire document particularly Table 1).

For present claims 13-15, Peterson et al. teach gold SPR substrate (e.g. gold on glass; please refer to entire document particularly Materials and Methods section).

For present claim 16, Peterson et al. teach probes 25 base pairs in length (please refer to entire document particularly Table 1).

For present claim 17, Peterson et al. teach incubation at room temperature (e.g. 25°C; please refer to entire document particularly Materials and Methods).

Therefore, the presently claimed invention is anticipated by the teachings of Peterson et al.

# Arguments and Response

16. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Peterson et al. for claims 1-9 and 11-18 were considered but are not persuasive for the following reasons.

Applicants contend that Peterson et al. does not teach co-adsorption.

Applicants' arguments are not convincing since the teachings of Peterson et al. anticipate the methods of the instant claims. Peterson et al. teach preparing solutions of probe, target, and duplex and immobilization wherein a gold substrate is exposed to a DNA solution comprising HSC<sub>6</sub>-DNA (i.e. co-adsorption; please refer to the entire specification particularly Materials and Methods section; Table 1).

In response to applicant's arguments, the recitation "co-adsorption" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

17. Claims 1-9, 11-13, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bawendi et al. U.S. Patent 6,855,551 filed April 12, 2001 (effective filing date September 18, 1998).

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For present claims 1, 3-4, 6-9, 11-12, Bawendi et al. teach methods of making semiconductor nanocrystals/quantum dots comprising (a) bringing a quantum dot (e.g. solid phase substrate) into contact with nucleic acid probes including HS-alkylene-PEG wherein alkylene is C<sub>6</sub> and a HS-alkylene-hydroxyl compound wherein the alkylene includes C<sub>6</sub> and (b) incubating the solid phase and the nucleic acid and HS-alkylene-hydroxyl compound (please refer to the entire specification particularly abstract; Figures 3-4, 6, 8-9; columns 4-14; Examples 1-10). Please note: the Office does not have the facilities and resources to provide the factual evidence needed in order to determine the concentration of the nucleic acids and compounds taught by Bawendi et al. or the ratio of the nucleic acids and compounds taught by Bawendi et al. correlate to the 60/40 or 40/60 ratio as presently claimed in claim 8. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the ration is different from the ones taught by the prior art and to establish the patentable differences. See in re Best 562F.2d 1252, 195 U. S. P. Q. 430 (CCPA 1977) and Ex parte Gray 10 USPQ2d 1922(PTO Bd.Pat. App. & Int. 1989).

For present claim 2, Bawendi et al. teach DNA and RNA (please refer to the entire specification particularly columns 4, 6-7, 9-14).

For present claim 5, Bawendi et al. teach polyethylene glycol (please refer to the entire specification particularly column 8).

For present claim 13, Bawendi et al. teach quantum dots made of metal (please refer to the entire specification particularly column 5; Examples 1-2).

For present claim 17, Bawendi et al. teach room temperature (e.g. 25°C; please refer to the entire specification particularly Examples 9-10).

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al.

Therefore, the presently claimed invention is anticipated by the teachings of Bawendi et

# Arguments and Response

Applicants' arguments directed to the rejection under 35 USC 102 (e) as being 18. anticipated by Bawendi et al. for claims 1-9, 11-13, and 17 were considered but are not persuasive for the following reasons.

Applicants contend that Bawendi et al. does not teach co-adsorption.

Applicants' arguments are not convincing since the teachings of Bawendi et al. anticipate the methods of the instant claims. Bawendi et al. teach quantum dot-oligonucleotide complex formation (i.e. co-adsorption; please refer to the entire specification particularly Examples 5-6 and 9-10; Figures 3-9).

In response to applicant's arguments, the recitation "co-adsorption" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time 19. policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor. Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS October 19, 2007

> MARK L. SHIBUYA PRIMARY EXAMINER

Mark 2. Shily